FEB 11 2003

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is provided as part of this Premarket Notification to comply with the provisions of the safe Medical Devices Act of 1990 requiring that either a summary be included in a submission or a statement that a summary is available upon request.

Submitter

Robert V. Price
HydroPure Systems, Inc.
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July 23, 2002

Device Names

Trade Names

HydroPure "Acute" Portable Exchange Deionization (PEDI) System
HydroPure "Central" PEDI System
HydroPure "Back-up" PEDI System

Common or usual name

Deionization systems with pre & post treatment and product water distribution components.

Classification name

Water purification systems for hemodialysis (21CFR 876.5665)

Intended Use

HydroPure Deionization Systems with pre & post-treatment and product water distribution components are intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysis concentrates to form dialysate, reprocessing of hemodialyzers and equipment rinse and disinfection.

Device Description

The HydroPure systems purify potable feed water through deionization. Deionization is used to remove 99.99+% of ions from water. Deionization alone does not remove particulates, organics, bacteria, viruses or endotoxins. The systems require adequate pretreatment and post-treatment. Deionizers are designed for the hemodialysis application to treat RO or carbon filtered potable water. Inappropriate use can result in the formation of Nitrosamines in the effluent of the deionizer.

The purpose of the pretreatment section of the system is to condition the feed water supplying the deionizers. Conditioning the feed water will include: pressure reducing valves to regulate system pressure, check valves to prevent back-flow of the treated water into the potable water source, cartridge filters to reduce particulates and sediment, carbon filtration tanks to remove chlorine/chloramines and sample ports after each carbon tank to check feed water conductivity and for any chlorine/chloramine residual.

The purpose of the post-treatment section of the system is to remove bacteria and endotoxins or lower them to acceptable levels as required by the AAMI standards. The post-treatment section of the system will include: submicron/ultrafilters after the deionizers, sample ports to check for microbial contamination and to test for comprehensive AAMI analysis, a 200K ohm quality control light at mid tank and a temperature compensated audible visual resistivity alarm set at one megohm or greater for final water quality. A remote alarm will be installed if the deionization system is not located in the patient treatment area. A distribution section of a system is necessary to deliver product water that meets ANSI/AAMI standards to the points of use. During use, continual monitoring of the effluent through the use of the temperature compensated audible and visual resistivity alarm is required. Routine monitoring of the mid tank quality indicator is also required on intervals during the day, at least before and after each patient treatment.

Should final water quality fall at or below 1 megohm, the alarm will sound and light up red and all patient treatments must be discontinued. The deionization tanks must be replaced as per Appendix C of the operating manual prior to resuming any patient treatment.

Depending upon the PEDI system size and feed water quality of 10grains TDS, HydroPure systems produce typically 250 gallons per deionization tank exchange at a flow-rate of up to 0.75gpm, to 3,600 gallons per deionization tank exchange at a flow-rate of up to 15gpm.

HydroPure's water purification systems will produce product water that meets the requirements of the standard issued by the American National Standard Institute and the Association for the Advancement of Medical Instrumentation: ANSI/AAMI RD62:2001, Water Treatment Equipment For Hemodialysis Applications.

Predicate Device

The Hydropure PEDI Systems and pretreatment and product water distribution components are substantially equivalent to US Filter Corporation's water treatment system for dialysis which utilizes carbon and deionization cylinders to purify water for hemodialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2003

Mr. Robert V. Price
President
HydroPure Systems, Inc.
3319 Bartlett Blvd.
ORLANDO FL 32811

Re: K022747
Trade/Device Name: HydroPure Systems, Inc. PEDI Water Purification Systems for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: December 11, 2002
Received: December 17, 2002

Dear Mr. Price:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K022747

Device Name: HydroPure "Acute" Portable Exchange Deionization (PEDI) System
HydroPure "Central" PEDI System.
HydroPure "Back-up" PEDI System

Indications For Use:

The HydroPure "Acute" Portable Exchange Deionization (PEDI) System consists of two each small carbon and mixed bed DI tanks with pre & post-filtration. It is intended to be placed on the back of a dialysis machine or on a handcart for single patient dialysis.

The HydroPure "Central" PEDI System consists of two or more carbon and mixed bed DI tanks with pre & post-filtration. It is intended to be installed in a central location for multiple patient dialysis.

The HydroPure "Back-up" PEDI System consists of two or more mixed bed DI tanks as a component in a "back-up" condition when a RO system or major component on a water purification system for hemodialysis is in need of repair. It may also be used in DI polishing mode to remove ions that an RO could not lower to safe levels.

All three PEDI systems with appropriate pre & post-filtration and components is intended for use with a hemodialysis system to remove organic and inorganic substances from water that is used to dilute dialysis concentrates to form dialysate and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022747